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2013 President's Report

Robert A. Menotti, MD, FACS, President
Medical Liability Mutual Insurance Company

Medical Liability Mutual Insurance Company (MLMIC) is the leading medical liability insurer in New York. We insure approximately 16,000 physicians, 5,000 mid-level practitioners, 4,000 dentists and 40 hospitals, and have about a 33% market share statewide (excluding self insurance). MLMIC is a mutual insurance company, which is owned by its policyholders. Our mission is to provide the highest quality liability insurance at the lowest possible cost consistent with long term viability. MLMIC employs about 400 people in four offices throughout New York (Manhattan, Latham, Syracuse, and East Meadow) and has been successfully meeting the needs of its policyholder owners since 1975.

In 2013, MLMIC paid a 3% dividend to its physician, mid-level practitioner, and hospital policyholders (5% for dentists), which provided some needed relief in today's challenging environment. Our policyholders continue to experience reimbursement and operational challenges associated with healthcare reform at the state and national level. As a mutual insurer, we constantly try to provide relief, when it is financially prudent to do so, via policyholder dividends or rate reductions in areas where it is actuarially indicated. As such, in 2013, MLMIC reduced rates 5% in 3 geographic regions in New York that favorably impacted over 50% of our insured physicians and mid-level practitioners. We held rates flat for dentists, and kept rate increases on insured hospitals to a minimum. Through active risk management, experienced claims handling and expert legal advice, we continue to close the vast majority of claims against policyholders with no payment to plaintiffs. We also keep a close eye on operating expenses, and continue to report one of the lowest operating expense ratios for our peer group in New York and the U.S.A.

In 2014, we expect that our policyholders will continue to face reimbursement and operational challenges associated with healthcare reform. We plan to pay a 5% dividend to all policyholders in 2014, and will look to maintain rates at the actuarially indicated minimum level. Our financial condition remains strong, with over $5 billion in assets and more than $1 billion in policyholder surplus (i.e., assets in excess of liabilities). We know from past experience that financial results can erode quickly when claim costs suddenly increase, and hence the importance of a surplus to cushion these occurrences. Some in our business do not have a surplus, or have only a modest one, and thus are vulnerable to financial strain should claim costs suddenly increase or investments suddenly decline.

Finally, beginning in May, you'll see a new look, tone and feel to our website, policy forms, and advertising. Our goal is to make it easier for policyholders and prospects to do business with us. We believe our strength, experience and commitment to policyholder-first service position us well to respond to the needs of our existing policyholders, and to accept new ones entering the market or switching from other carriers.

Thank you for giving us the opportunity to serve you. We look forward to another successful year in 2014.

Sincerely,
Robert A. Menotti, MD

Physician Assistants: A Risk-Benefit Analysis

Mirsade Markovic, Esq.
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Counsel to Medical Liability Mutual Insurance Company

Physician assistants (PAs) can benefit physicians' practices by performing various medical duties involving care and treatment of patients. However, physicians who supervise PAs can potentially face liability for the acts and/or omissions of these PAs.

This article explores the role of PAs, the various types of liability that may occur, and how to minimize the risks associated with such liability.

The General Benefits of Utilizing Physician Assistants

Physician assistants provide a number of benefits to the practices that employ them: they allow such practices to service more patients by performing many of the same functions as a physician; they free up the time of physicians to treat conditions that may be beyond the capabilities and qualifications of PAs; and they can increase patient satisfaction by spending more time with patients, and by seeing patients more quickly.

In the office and hospital settings, PAs can improve physician-patient communication, which can translate into improved patient care. In the office, they can triage and return telephone calls, review test results, and contact other medical providers. Since PAs can provide more one-to-one time during patient encounters, they can use this time for both treatment and to educate patients about health, lifestyle choices, and/or proper pre-operative and discharge instructions.

What Medical Duties May Physician Assistants Perform in an Office and Hospital Setting?

Physician assistants may perform tasks delegated by supervising physicians. These tasks must be appropriate to the PAs' education, training, and experience and be within the ordinary practice of the supervising physician.[1] Supervision of PAs is considered continuous, but physicians are not required to be physically present when PAs are providing services.[2] PAs may have more than one supervising physician, but one clearly designated supervising physician must be available at all times.[3]

Physician assistants are dependent practitioners who must work under the supervision of licensed physicians who are then considered by New York State courts to be legally responsible for the acts and/or omissions of the PAs.[4]

Guidelines issued by the New York State Department of Health specifically define those acts which can be performed by PAs as follows:[5]

1. **Evaluation** – Obtain a detailed and accurate history from each patient, perform an appropriate physical examination, delineate problems, and record/present data.
2. **Monitoring** – Assist supervising physicians in conducting rounds in acute and long term inpatient settings, provide care in office-based and ambulatory care settings, develop and implement patient management plans, and record progress notes.
3. **Diagnostics** – Perform and/or interpret, at least to the point of recognizing deviations from the norm, common diagnostic procedures used to identify disease processes.
4. **Therapeutics** – Perform routine procedures such as injections, immunizations, suturing and wound care; manage simple conditions caused by infections or trauma, assist in the management of more complex illnesses and injuries; take the initiative in the evaluation of patients and initiation of therapeutic procedures in response to life-threatening situations; and supervise and direct blood testing to determine blood alcohol or drug levels relative to potential violations of the Vehicle and Traffic Law.[6, 7]
5. **Counseling** – Instruct/counsel patients regarding compliance with prescribed therapeutic regimens, normal growth and development, family planning, emotional problems of daily living, and health maintenance.
6. **Referral** – Facilitate and refer patients to other health-related practitioners and community health and social services agencies, when appropriate.[5]
7. **Medical Orders** – Write medical orders, including those for controlled substances, for inpatients under the care of their supervising physi-

1. Public Health Law § 3703, Education Law § 6542(1).
2. Education Law § 6542 (2), 10 N.Y.C.R.R. § 94.2 (a).
3. Reference Information: Registered Physician Assistant, New York State Department of Health, (February 2014) at Section D. Accessed at http://www.health.ny.gov/professionals/doctors/conduct/physician_assistant.htm on February 19, 2014.
4. Marchisotto v. Williams, P.A., et. al., 11 Misc. 3d 1089 (A), (N.Y. Sup. Ct., 2006).
5. Reference Information: Registered Physician Assistant, New York State Department of Health, (February 2014) at Section B. Accessed at http://www.health.ny.gov/professionals/doctors/conduct/physician_assistant.htm on February 19, 2014.
6. Public Health Law § 3702 (2).
7. Vehicle and Traffic Law § 1194 (4)(a)(1).

cian, without a countersignature. Supervising physicians and/or the hospital may delineate situations in which PAs' orders must be countersigned. However, a countersignature is not required prior to the execution of PAs' orders.[8]

8. **Prescriptions** – Prescribe medications, in both the office and hospital settings, including controlled substances in Schedule III – V, if these tasks have been delegated by a supervising physician.[9] Currently, PAs may not prescribe any controlled substance in Schedule II.[10] Prescriptions may only be written for patients who are under the care of the supervising physician.[11] Prescriptions for non-controlled medications written by PAs must be placed on a supervising physician's prescription form, which must include: the name, address, and telephone number of the physician; the name, address, and age of the patient; and the date upon which the prescription was written.[12] Prescriptions for controlled substances listed in Schedules III – V may be written on prescription forms issued to PAs. PAs must include the printed name of the supervising physician, their own printed and signed name, the initials RPA or RPA-C, and their New York State registration number.[13] When prescribing controlled substances, PAs must also comply with the New York State Prescription Monitoring Program (I-STOP Law).[14]

8. Public Health Law § 3702 (1).
9. Public Health Law § 3702 (3).
10. 10 N.Y.C.R.R. § 94.2 (e)(5).
11. 10 N.Y.C.R.R. § 94.2 (e)(1).
12. 10 N.Y.C.R.R. §94.2(e)(1).
13. 10 N.Y.C.R.R. § 94.2 (e)(3),(4).
14. Public Health Law § 3343-a.

What Duties May Physician Assistants Not Perform?

Physician assistants are prohibited from performing radiological procedures, practicing optometry,[15] and signing death certificates. Further, PAs may only act as a first assistant for surgical procedures which do not present unusual hazard to life based on individual patient risk factors and complexity of the procedure.[16]

What Types of Liability Do Supervising Physicians Have for Physician Assistants?

Supervising physicians have direct liability for their own actions, which can include negligent supervision. Supervising physicians' direct liability results when it is proven that injury to a patient is a result of physicians' negligent supervision, rather than the actions of a PA. Therefore, supervising physicians may be liable even if PAs are not found to be negligent.

Factors to be considered when courts assess whether physicians have provided appropriate supervision of PAs include: the presence or absence of physicians; which responsibilities are delegated to PAs; the presence or absence of medical records; and the maximum number of PAs a physician may supervise. New York State regulations allow the supervision of four PAs in the office setting, and six PAs in the hospital and correctional facility settings.[17] Supervising physicians who fail to provide adequate supervision for PAs may also face allegations of professional misconduct.[18]

Supervising physicians or hospitals may face direct liability for allegations of negligent hiring if the individuals who hired PAs knew, or should have known, that the PAs were unqualified or otherwise unfit to perform the professional services they were assigned to perform. Physicians or hospitals may also be held liable if the hiring individuals fail to use due diligence, prior to hiring PAs, to ascertain if they are

15. Reference Information: Registered Physician Assistant, New York State Department of Health, (February 2014) at Section B. Accessed at http://health.ny.gov/professionals/doctors/conduct/physician_assistant.htm on February 19, 2014.
16. 10 N.Y.C.R.R. § 405.12 (a)(3). The addition of Public Health § 3703 does not override 10 N.Y.C.R.R. § 405.12. The new legislation is not intended to expand or limit the scope of practice of a physician assistant. E-mail opinion Walter Ramos, R.N., J.D., State Department of Education Board for Medicine, April 14, 2010.
17. Clinical settings: Public Health Law § 6542 (2). Hospitals: 10 N.Y.C.R.R. § 405.4 (e)(1)(ii)(a). Correctional facilities: Public Health Law § 6542 (5).
18. 8 N.Y.C.R.R. § 29.2 (a)(5).

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capable of performing the duties to which they will be assigned.[19]

Supervising physicians also have vicarious liability, even if they acted appropriately, for the actions of the PAs they supervise.[20] Vicarious liability is an "attachment of responsibility to a person for harm or damages caused by another person in either a negligence lawsuit or criminal prosecution. Thus, employers of PAs who injure someone through negligence while in the scope of employment (doing work for employers) are vicariously liable for damages to injured persons."[21]

The most common form of vicarious liability is respondeat superior ("let the superior respond"). Under this theory, if PAs perform negligent acts and it is determined that supervising physicians could have controlled their activity, supervising physicians can be found liable. Additionally, patients must reasonably believe that PAs had the authority to act on behalf of the supervising physicians.[22] Under this legal theory, physicians do not have to be present or even aware of the patient encounter.

Findings of vicarious liability may still be possible against supervising physicians, despite the dismissal of PAs from a lawsuit.[23] If a supervising physician has terminated the employment of a PA, a claim can still be pursued against a supervising physician, based upon the theory of vicarious liability. Therefore, a PA does not necessarily have to be a named defendant for the lawsuit to solely focus on the supervising physician, based upon the theory of vicarious liability.

How to Minimize Supervising Physicians' Risk of Liability for Physician Assistants

1. Every practice or hospital employing PAs should have comprehensive protocols and policies that outline what conditions PAs may handle independently and what requires consultation with a supervising physician. These protocols may include:
   a. limiting the number of times a patient sees a PA without seeing a supervising physician and
   b. specifying the types of illnesses or conditions that must only be handled by the supervising physician.
2. It is important to discuss the protocols and policies with PAs to confirm that they both understand and will comply with them. Both supervising physicians and PAs should sign a document to confirm their understanding of, and agreement with, the terms of employment, including compliance with all policies and protocols.
3. Supervising physicians must be readily available and approachable. PAs should always have reliable contact information for supervising physicians. Additionally, PAs should never be afraid to approach supervising physicians with questions and/or concerns, no matter how trivial the question may seem. Fear of disturbing physicians or of being made to feel inadequate can deter PAs from seeking consultation. Thus, the patient may not receive appropriate treatment and/or be incorrectly diagnosed.
4. Meetings should be regularly scheduled between supervising physicians and PAs to discuss cases and how they were handled. This can be beneficial and educational, as well as promoting interactive relationships between supervising physicians and their PAs. When specific cases are reviewed, PAs may greatly benefit by learning to recognize which symptoms and conditions should be discussed with supervising physicians.
5. Supervising physicians should regularly check the work habits of PAs. One way to do this is to ask patients who have seen a physician assistant several times about their experiences. Physicians can also observe PAs as they provide treatment and obtain histories from patients.
6. Supervising physicians should perform and document periodic evaluations (at least annually) of all PAs as well as regular reviews of a sampling of the medical records.
7. PAs must document in the patient's medical record any recommendations made by supervising physicians after any consultation.
8. All continuing education activities should be attended by both PAs and the supervising physicians. This keeps current their knowledge and skills. Continuing education assists the PAs in recognizing the significance of findings discovered during a physical examination that is beyond their expertise. This should prompt communication between PAs and supervising physicians.
9. It is important to be diligent in hiring, training and supervising PAs. In order to minimize the risk of being sued for the negligent hiring of a physician assistant, supervising physicians must use due care during the hiring process. PAs must have the education, training and certification required by law, and physicians should verify these from a primary source. A criminal background check should also be performed. Supervising physicians should also obtain written permission from PAs to contact and speak with all past supervising physicians, even those not listed as references.

19. Page, Alexandra E., MD, Liability Issues with Physician Extenders, AAOS Now, March 2010. Accessed at http://www.aaos.org/news/aaosnow/mar10/managing6.asp on February 20, 2014.
20. Page, Alexandra E., MD, Liability Issues with Physician Extenders, AAOS Now, March 2010. Accessed at http://www.aaos.org/news/aaosnow/mar10/managing6.asp on February 20, 2014.
21. Law.com Legal Dictionary/vicarious liability. Accessed at http://dictionary.law.com/Default.aspx?selected=2223 on March 3, 2014.
22. Page, Alexandra E., MD, Liability Issues with Physician Extenders, AAOS Now, March 2010. Accessed at http://www.aaos.org/news/aaosnow/mar10/managing6.asp on February 20, 2014.
23. Pace v. Hazel Towers, 584 N.Y.S.2d 22, 22 (1st Dept, 1992).

Professional Liability Coverage for Physician Assistants

In addition, when hiring PAs, physicians should confirm that the individuals have professional liability coverage with appropriate limits of liability should a lawsuit ensue. It is important to be aware that PAs who are insured by a MLMIC policy would have their coverage limited to those acts and duties which are within the scope of their employment by a MLMIC insured employer. Therefore, any contract between physicians and PAs must specify the scope of employment of PAs.

Case law has determined that physicians are liable for services provided by individuals for whom they are legally responsible (e.g., PAs). However, physicians' professional liability insurance does not provide coverage for those individuals.[24] Consequently, it is highly advisable that PA's obtain their own individual policy of insurance.

In summary, hiring PAs to treat patients has many advantages if they have the necessary education, training, and experience to perform those acts which are within the scope of practice of supervising physicians. However, it is also important that supervising physicians ascertain the competency of PAs, and obtain written verification of their education, training, and prior experience. It is also crucial to keep the lines of communication open so that PAs feel free to contact the supervising physicians, when needed, and ask for assistance. Finally, at least initially, supervising physicians should review PAs' documentation to check their diagnostic skills and initially have PAs request consultation for certain signs, symptoms, or conditions until the physicians are comfortable with their competence. This will act to mitigate physicians' risk of liability. ❖

24. Cohen v. Medical Malpractice Ins. of N.Y., 868 N.Y.S.2d 14, 14 (1st Dept, 2008).

Case Study

Negligent Post-Surgical Patient Care

John Neuburger, Assistant Vice President, Claims
Medical Liability Mutual Insurance Company

This case involves the alleged wrongful death of a 43-year-old certified public accountant who was married with three children. At the time of his death, the decedent was earning $130,000 per year. He died following surgery for the removal of a large cell neuroendocrine carcinoma of the right lower lobe of the lung.

The patient was initially seen by his primary care physician with complaints of chest pain and cough in January of 2008. A lung mass was noted on x-ray. A fine needle aspiration confirmed the diagnosis of cancer. The patient was referred to a surgeon for a surgical resection. The surgical group consisted of three physicians and four mid-level practitioners. Pre-operative clearance was obtained, and, in February of 2008, the surgeon performed a right lower lobectomy. There were no complications during surgery and the estimated blood loss was 200 cc. The patient did well immediately after surgery and throughout the night in the surgical ICU. During the night, 30 cc. of bloody fluid drained from the anterior chest tube and the posterior chest tube had 50 cc. of drainage.

In the morning, as the patient was assisted to a sitting position on the side of the bed, he became dizzy and was promptly returned to a lying position. The hospital's nursing staff noted the anterior tube had 200 cc. of drainage and the posterior tube had 500 cc. of bloody drainage. A PA from the surgical group examined the patient at 7:30 AM. This PA had recently been hired by the surgical group. He had previously worked in an internal medicine office and had limited experience with surgical patients. He was not familiar with the post-operative treatment of thoracic surgery patients and admitted to being inexperienced with the complications which can and do sometimes occur in the immediate post-operative period. He also lacked familiarity with the type of tumor removed from the patient.

When the PA examined the patient, the patient's blood pressure was 90/62. Two boluses of 500 cc. of saline were given to him with slight improvement. At 9:00 AM, the PA called the operating surgeon. Documentation of this call contained no content other than the fact that the surgeon had been called. The chest tube drainage continued to increase, while the patient's hematocrit dropped to 22. In response to this, the PA ordered two units of blood to be given. At 10:00 AM the patient's blood pressure was 81/52. He continued to deteriorate. A code was called at 10:30 AM. Resuscitative efforts were unsuccessful. The patient was pronounced dead at 11:45 AM. An autopsy determined that the cause of death was post-operative bleeding with a right hemothorax.

It was apparent that the PA had been placed into a difficult and high-risk situation by the surgical group. He had to deliver care to a critically ill post-operative patient but lacked expe-

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Case Study

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rience and proper orientation to post-operative patients. Given this limited experience in managing post-operative surgical patients, he failed to appreciate the grave nature of the patient's condition. Nor did he insist upon receiving additional assistance from the physicians in the surgical group. The patient's family commenced a lawsuit against the surgeon, the physician assistant, and the hospital. After careful review of the case by MLMIC experts, it was found to be indefensible. Therefore, settlement talks commenced.

The initial settlement demand from our two insured defendants, the PA and the surgeon, was $2 million. The plaintiff's theories of liability for the hospital, PA, and surgeon included failure to properly diagnose, appreciate, communicate, or treat a significant life threatening peril with imminent danger to the decedent. It was alleged the defendants collectively failed to properly manage, monitor, and care for the decedent, leading to his death.

The lawsuit ultimately was settled on behalf of the PA and surgeon for $1.5 million. The PA was apportioned 80% of that amount ($1.2 million) and the remaining 20% ($300,000) was apportioned to the surgeon. The codefendant hospital, which was not insured by MLMIC, contributed an additional $150,000, resulting in a total settlement of $1.65 million.

A Legal & Risk Management Perspective

Donnaline Richman, Esq.,
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Counsel to Medical Liability Mutual Insurance Company

There are several key issues of risk management and legal importance which are immediately evident in this case. The PA was admittedly unfamiliar with the tumor and the procedure the patient had undergone, and failed to timely recognize the significance of the patient's symptoms, such as increasing bloody drainage from the chest tubes. It appeared he lacked sufficient education about, and experience in the area of, surgical practice. His prior experience did not involve surgical or critical care patients.

The physicians who hired this PA, and particularly the supervising physician, should have determined whether this PA had the requisite training, education, and experience to carry out the duties of this position. A closer assessment of this PA's background experience and skills might well have shown the deficits in his experience and knowledge before he was placed in a surgical position. There is a very clear difference between the diagnostic experience of a PA in a medical practice versus that of a PA in a surgical practice. Unfortunately, the PA and the surgeons should have recognized this and encouraged the PA to seek relevant education and, perhaps, additional training experiences, before having him become responsible for assessing and treating critically ill surgical patients. Even if the group had utilized another employed PA to act as this PA's mentor, it remained the duty of the physicians to assess the PA's competence and properly orient him to surgical care before placing him in this position. Unfortunately, despite being placed in an unfamiliar and difficult situation with this post-operative patient, the PA apparently did not feel sufficiently comfortable to convey his concerns to the supervising physician, and, more particularly, to request his timely presence and advice.

Finally, not only did the PA fail to recognize the critical changes in the patient's status, he failed to document his diagnosis of the cause of these changes, as well as the content of his discussion with the supervising physician. The supervising physician was equally at fault for not ascertaining whether the PA was both appropriately treating this patient and cognizant of the seriousness of the change in his status.

There was also no evidence that the surgical group had provided the PA with specific criteria for when the PA should have contacted the attending supervising physician to request that the attending come in to see the patient. Practices and mid-level practitioners must have, and be familiar with, defined policies and protocols for the treatment of patients in the post-operative and critical care areas. This recommendation cannot be overstated. The skills of a new PA must be thoroughly evaluated by a physician before the PA is allowed to proceed to the next level of care. Both the PA and physician should be comfortable with the appropriateness of the PA's skills and experience. Teaching and educational sessions for both physicians and PAs should be implemented to encourage continued learning and increased interaction between physicians and PAs. None of that occurred in this case, leading to the patient's demise. ❖

When a Patient Requests a Refund, How Should You Respond?

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Counsel to Medical Liability Mutual Insurance Company

Despite your best efforts, there are always patients who will, for some reason, demand a refund of what they have paid you for professional services. When this occurs, there are several steps you must take.

You must as soon as reasonably possible contact the Claims Department of your liability carrier, Medical Liability Mutual Insurance Company (MLMIC) and report this demand for a refund. If you do not notify MLMIC and the patient later brings a lawsuit, your coverage under your policy may be compromised.[1]

You should then ask the patient to advise you of a definite sum they wish to have refunded and inquire why the patient is demanding a refund. Once you have that information, you can begin to review the patient's record and then make a decision. It is never a good idea for you to respond immediately to a patient's verbal demand. Further, you must never admit liability. We recommend that you advise the patient that you will review and investigate the demand. That gives you time to think about how you wish to respond, based upon the exact sum of money that the patient has committed to, and, perhaps, help you to understand why the patient is unhappy. It is important to provide the patient with a time frame within which he or she can expect a response (e.g., two weeks). This helps to protect you from constant telephone calls and/or emails. If you wish to deny this refund request, you may ask to speak to an attorney at Fager Amsler & Keller, LLP, who can assist you with your response.

On the other hand, if you and MLMIC have determined that a refund is acceptable to you, regardless of the amount, Fager Amsler & Keller attorneys are available to assist you in the preparation of all documents necessary to successfully and safely complete the arrangement. This would include the preparation of a General Release, which is a legal document that should only be prepared in conjunction with counsel.

It is important to understand that if there is to be a refund of the fees the patient has paid out of your personal funds,[2] you must first determine who actually paid your professional fees. If

1. Section IV 1 of the Physicians & Surgeons Professional Liability Policy provides that: You or the Professional Entity must take immediate action if a Claim is made against an Insured or if you or the Professional Entity become aware of an incident which could reasonably lead to a Claim against an Insured in the future. A Claim must be reported by you, on your behalf, or by the Professional Entity to us or to any licensed agent of ours in New York as described below. If you or an Insured receive notice of a Suit or Claim against an Insured, you or the Professional Entity must notify us or our licensed agent in writing as soon as reasonably possible. If you or the Professional Entity become aware of any incident which could reasonably lead to a Claim against you or any Insured in the future, you or the Professional Entity must notify us as soon as reasonably possible. Section IV 2b of the Physicians & Surgeons Professional Liability Policy provides that: Insureds must not make any payments or any statement to any claimant that might give rise to an implication of liability, nor may an Insured make any agreement or settlement with any claimant or possible claimant without our prior written authorization. If an Insured does any of these things, they may jeopardize coverage under this policy.

2. NPDB Guidebook Sept. 2001 E-10: Individual subjects are not required to report payments they make for their own benefit to the NPDB. On August 27, 1993, the Circuit Court of Appeals for the District of Columbia held that [445 (DC Cir. 3 F.3D 1993)] the NPDB regulation requiring each "person or entity" that makes a medical malpractice payment was invalid, insofar as it required individuals to report such payments. The NPDB removed reports previously filed on medical malpractice payments made by individuals for their own benefit. A professional corporation or other business entity comprised of a sole practitioner that makes a payment for the benefit of a named practitioner must report that payment to the NPDB. However, if a practitioner or other person, rather than a professional corporation or other business entity, makes a medical malpractice payment out of personal funds, the payment is not reportable.

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NEW Developments

New CLIA Amendment Allows Patients to Directly Access Laboratory Results

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On February 6, 2014, the U.S. Department of Health and Human Services published amendments to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regarding a patient's right to access his or her laboratory test results.[1] These amendments grant patients the right to access their test results directly from clinical laboratories, including completed laboratory test reports, without first having to contact their medical providers.[2] The new rule became effective on April 7, 2014 with a compliance date of October 6, 2014.

The existing New York State regulation on this subject, 10 NYCRR § 58-1.8, states that laboratory test results cannot be reported directly to the patient "except with the written consent of the physician or other authorized person." This regulation now conflicts with the new Federal law, and, therefore, in a bulletin dated February 19, 2014, the New York State Department of Health advised that the State regulation will be repealed to comply with Federal rules.

The new Federal law allows an individual or an individual's personal representative (as that term is defined by HIPAA) to request and receive completed test reports directly from a laboratory that is a HIPAA-covered entity. Laboratories must provide results no later than 30 days after receipt of a request for test results. The Department of Health recommends that laboratories and/or EHR systems have a mechanism to ensure that the practitioner who ordered the test has an opportunity to review and discuss the test results with the patient. The 30-day window will ensure that, in accordance with good medical practice, there is enough time for the practitioner who ordered the test to communicate with the patient regarding the test results.

Both State and Federal law will continue to allow healthcare professionals to deny patients access to laboratory test results on the grounds that the access requested is reasonably likely to endanger the life or physical safety of the patient or another person.

1. 42 CFR Part 493 and 45 CFR Part 164.
2. https://www.federalregister.gov/articles/2014/02/06/2014-02280/clia-program-and-hipaa-privacy-rule-patients-access-to-test-reports.

The Justice Center Act

New York State has enacted a law which established the Justice Center for the Protection of People with Special Needs. The law became effective on June 30, 2013. (877) 373-2122 is the statewide toll free hotline for the incident reporting system known as the Vulnerable Persons' Central Register (VPCR). This registry tracks reports of possible abuse and neglect, 24 hours a day.

A vulnerable person is defined as: a person with a physical or cognitive disability; or a person who requires services or placement or who receives care from a facility or provider governed by New York State agencies. Vulnerable persons include: patients who have developmental disabilities or mental health conditions; persons receiving services for alcohol and substance abuse from a state registered agency; children in custody of the Office of Family Services; and individuals in the New York State Schools for the Blind and the Deaf, among others.

If a mandatory reporter has reasonable cause to suspect a reportable incident has occurred involving a person with special needs, a report must be made. Reportable incidents include, but are not limited to: physical or mental abuse; neglect; sexual, financial or emotional exploitation or risks of the above; and inappropriate restraint or seclusion.

Mandated reporters include: human services professionals who work with persons with special needs; hospital personnel; physical therapists; occupational therapists; a variety of mental health professionals and therapists; nurses; physicians and other medical/nursing advanced practitioners; social workers; and school personnel. This is similar to those mandated to report child abuse to the Child Protective Service. However, anyone else can call the hotline, even if not mandated to do so.

Reporting must be completed immediately upon discovery of a reportable incident, unless a delay, such as needing to call EMTs, is necessary to prevent harm. However, the report must be made no later than 24 hours from the time it is determined that there was reasonable cause to believe that a reportable incident occurred.

After receiving the report, the Justice Center will then collaborate with local law enforcement, state police, and district attorneys to prosecute those who are involved in the incident, if indicated.

Guidance Released On De-Identification of Protected Health Information

The HIPAA Privacy Rule protects individually identifiable health information held or transmitted by a covered entity or its business associate, in any form

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Advertising and Providing Medical Advice over the Internet: Cautions and Concerns

Robert Pedrazzi, Assistant Vice President, Underwriting
Medical Liability Mutual Insurance Company

With the expansion of Internet social media encompassing all types of businesses, including the practice of medicine, physicians may become enticed to participate on the many platforms that are available to them. Aside from standard websites or Facebook pages providing basic information about your group or practice, the offering of additional services, such as the ability for both patients as well as non-patients to schedule appointments or seek medical advice, is vastly becoming the norm.

These services are undoubtedly a convenient means of promoting a group or practice. However, they do come with reasons for concern. It is important for physicians to be cognizant of the fact that their Physicians & Surgeons Professional Liability Insurance Policy (PSE) contains an important exclusion which pertains to this medium. This exclusion, as stated in our current coverage form for "Advertising, Publishing or Broadcasting Activity" in any format, including websites, is as follows:

> *This policy does not cover liability arising out of any advertising, publishing or broadcasting activity or for liability arising out of giving medical advice to a general audience by any means personally, electronically, or otherwise.*

However, PSE insureds providing professional services to a patient in their medical practice through electronic means such as email or video chat would likely by covered under the terms and conditions of their PSE policy. It is important to note that such activity is only coverable in the "Coverage Territory," which is defined in the policy as being:

a. any state of the United States, the District of Columbia, Puerto Rico or Canada, provided the Insured is duly licensed to practice medicine in that jurisdiction; or
b. anywhere in the world for liability arising from an emergency situation. In such cases, if we are prevented by law or lack of expertise from carrying out the defense and supplementary provisions of this policy we will reimburse any such expenses incurred by an Insured.

(Note: In order to be eligible for a MLMIC policy, the majority of a physician's practice must be in New York State.)

Furthermore, the insuring agreement of the policy states, in pertinent part, that the Company will pay claims that an insured becomes legally obligated to pay and that the Company will pay only if:

1. the Claim involves an allegation of injury to or death of a person or persons because of a Medical Incident that took place or Professional Services that were provided (or should have been provided) within the Coverage Territory; and
2. the Insured was duly licensed or certified, if required by law, in the jurisdiction where the Medical Incident took place or the Professional Services were provided (or should have been provided) at the time they were provided; and...

It is important to pay particular attention to the licensure requirements as stated in the above provisions of the policy. For coverage to exist, an insured physician must be duly licensed in both jurisdictions (physician and patient locations) when utilizing electronic communications in the performance of providing professional services with a patient from their medical practice.

An additional concern arises when providing professional services electronically to patients who are out-of-state. Such services may trigger another state's "long-arm" jurisdiction statute. These statutes confer jurisdiction over out-of-state individuals who are found to be "transacting any business in the state." This broad definition appears in, for example, the Alabama, Hawaii and Illinois long-arm statutes. Providing medical services certainly could be construed to fit within the statutory intent as far as "transacting any business" is concerned, and a physician whose services are alleged to have caused injury in this scenario could wind up defending a medical malpractice claim brought in another state.

Staying on the forefront of social media is crucial in today's competitive practice environment, as is having knowledge of the respective concerns inherent with such endeavors. The intent of this article is to bring awareness to our PSE insureds of some of the important issues surrounding this medium.

If you have any questions regarding policy exclusions or any other coverage matter, please contact your assigned underwriter in the regional office nearest you. ❖

RISK MANAGEMENT Tip

Tip #15 Communication With Patients

Communication is the cornerstone of the doctor-patient relationship. Patients' perceptions of physician communication skills may impact the potential for allegations of malpractice. The following are some suggestions which are designed to promote open communication and enhance your ability to reach an accurate diagnosis and develop an appropriate plan of care.

1. Employ active listening techniques and allow the patient sufficient time to voice their concerns.
2. Sit at the level of the patient and maintain eye contact.
3. Assess the patient's literacy level. This may be as simple as asking what is the highest grade level the patient attained. (http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy/index.html)
4. Use lay terminology when communicating with patients and their families.
5. Develop plans for communicating with patients who are hearing impaired, deaf, or have limited English proficiency (http://www.ada.gov/; http://www.hhs.gov/ocr/civilrights/resources/specialtopics/lep/).
6. Utilize the teach-back method when providing patients with instructions and information. This technique requires that patients repeat the information provided in their own words. The teach-back method is particularly useful in assessing patients' understanding of:
   a. Informed consent discussions
   b. Medication instructions including side effects and adverse reactions
   c. Test preparation
   d. Follow-up instructions

   If the patient is unable to convey the information, it should be restated in simpler terms, perhaps utilizing pictures and/or drawings.
7. Evaluate your educational tools and consent forms to determine the grade level at which they are written. This will allow you to provide written materials that will be understandable to the majority of your patient population. Techniques that determine the readability and comprehension levels of documents are available from numerous sources. (http://www.cms.gov/Outreach-and-Education/Outreach/WrittenMaterialsToolkit/downloads/toolkitpart07.pdf); (http://www.readabilityformulas.com/).
8. At the conclusion of your patient encounter, ask the patient/family if they have any questions or concerns that have not been addressed.
9. Medical record documentation should reflect all aspects of patient interactions and comprehension. This will demonstrate the effectiveness of your communication skills and promote patient satisfaction, which may reduce your potential exposure to claims of malpractice.

- Fullam F., Garman A.N., Johnson T.J., Hedberg E.C. 2009. *The Use of Patient Satisfaction Surveys and Alternative Coding Procedures to Predict Malpractice Risk.* Medical Care 47(5):553-9.
- Lown B.A., Gareis K., Kormos W., Kriegel G., Leffler D., Richter J., Ship A., Weil E., Manning C.J. 2013. *Communicate, Don't Litigate: The Schwartz Center Connections Program.* Journal of Healthcare Risk Management 33(1):3-10.
- www.jointcommission.org
- http://www.aaos.org/about/papers/advistmt/1017.asp ❖

When a Patient Requests a Refund *continued from page 9*

some or all of your fees were paid by an insurance company, you cannot return that portion of the money to the patient. Instead, any payment made by an insurer must be returned to that insurer. If the patient was "self-pay," then any amount paid may legitimately be refunded, if you choose to do so. If you are asked to "write off" an outstanding balance related to the patient's care and treatment rather than refund a fee, and the payment for those services was made by an insurance company, you must ascertain whether this is acceptable to the insurer. We recommend that you generate a paper trail regarding the request, your communications with the insurer, and your final decision.

Finally, if you have not already done so, you should consider whether you wish to formally discharge the patient from your practice. If a patient is that unhappy with your care as to seek a refund or demand monetary reimbursement, it is likely not in your best interests to continue a professional relationship with that patient.

The law firm of Fager Amsler & Keller, LLP is available to assist MLMIC insureds if they have any questions about requests for refunds, payment or to assist with drafting a Release of Liability after you have provided notice of the demand for the refund to MLMIC's Claims staff. If you have a question about a specific situation, please feel free to contact Fager Amsler & Keller, LLP at (877) 426-9555 (Syracuse); (516) 794-7340 (East Meadow); or (518) 786-2881 (Latham). ❖

MLMIC Library— A Policyholder's Resource

The MLMIC Library services are available to all policyholders on a complimentary basis and accessed via MLMIC.com under the Risk Management tab. The library was established to provide an additional layer of professional liability resources for our policyholders.

Books and DVDs are loaned on a complimentary basis and they are regularly reviewed to provide up-to-date answers and guidance for your risk management and patient safety questions.

In-depth research services are also available to all policyholders. Contact Judi Kroft, Library Services Administrator at 800-635-0666, ext. 2786 or via e-mail at jkroft@mlmic.com.

The following resources pertain to topics featured in this issue of *Dateline*. Visit the MLMIC Library to learn more about the titles and borrow up to five items from our extensive collection, at no charge to you.

- **2013 MLMIC Annual Risk Management Seminar: September 27, 2013.** Medical Liability Mutual Insurance Company; 2013 (Audio CD 561-178 2013).
- Suzanne Gordon. **Beyond the Checklist: What Else Health Care Can Learn From Aviation Teamwork and Safety.** ILR Press; 2013 (QA CQI 148-117).
- Roberta L. Carroll. **Enterprise Risk Management Handbook for Healthcare Entities.** American Health Lawyers Association; 2013 (R M 151-131 2013).
- **Essential Guide for Patient Safety Officers.** Joint Commission Resources; 2013 (R M 151-132 2013).
- Fay A. Rozovsky, et.al. **Health Care Credentialing: A Guide to Innovative Practices.** Aspen Publishers, Inc.; 2013 (Med Staff 113-085).
- Fay A. Rozovsky, et.al. **Health Care Organizations Risk Management: Forms, Checklists & Guidelines.** Aspen Publishers, Inc.; 2013 (R M 151-075 2013).
- **Medication Safety Officer's Handbook.** American Society of Health-System Pharmacists; 2013 (R M 151-142).

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Fager Amsler & Keller's attorneys are available during normal business hours to assist MLMIC insureds with a wide range of legal services, including, but not limited to, advisory opinions concerning liability issues, liability litigation activities, lecture programs, consulting services, and legal audits and assessments.

Healthcare law, regulations, and practices are continually evolving. The information presented in Dateline *is accurate when published. Before relying upon the content of a* Dateline *article, you should always verify that it reflects the most up-to-date information available.*

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NEW Developments *continued from page 8*

or medium, whether electronic, on paper, or oral. The Privacy Rule refers to this information as protected health information (PHI). Protected health information is information, including demographic information, which relates to:

- the individual's past, present, or future physical or mental health or condition;
- the provision of health care to the individual; or
- the past, present, or future payment for the provision of health care to the individual, and that identifies the individual, or for which there is a reasonable basis to believe can be used to identify the individual.

Protected health information includes many common identifiers (e.g., name, address, birth date, Social Security Number) when they can be associated with the health information listed above.

Identifying information alone, such as personal names, residential addresses, or phone numbers, would not necessarily be designated as PHI. The relationship with health information is fundamental. For instance, if such information was reported as part of a publicly accessible data source, such as a phone book, then this information would not be PHI because it is not related to health data. If such information was listed with a health condition, health care provision or payment data, such as an indication that the individual was treated at a certain clinic, then this information would be PHI.

The Privacy Rule limits the use and disclosure of PHI. However, health information can be very useful even when it is not individually identifiable. Therefore, the Privacy Rule permits a covered entity or its business associate to create information that is not individually identifiable by following the de-identification standard and implementation specifications found in 45 C.F.R. § 164.514(a)-(b). An entity is permitted to use and disclose information as long as it neither identifies, nor provides a reasonable basis to identify, an individual.

The Privacy Rule contains two de-identification methods: 1) a formal determination by a qualified expert; or 2) the removal of specified individual identifiers as well as absence of actual knowledge by the covered entity that the remaining information could be used alone or in combination with other information to identify the individual. On November 26, 2012, the Office for Civil Rights (OCR) in the US Department of Health and Human Services released formal guidance to inform providers about methods and approaches to achieve de-identification of protected health information. The guidance explains and answers questions regarding the two methods of de-identification. It is intended to assist covered entities in satisfying the standards for performing de-identification. This guidance can be found on the OCR website, http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html.

Regardless of the method by which de-identification is achieved, the Privacy Rule does not restrict the use or disclosure of de-identified health information, as it is no longer considered protected health information.❖